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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,505	01/21/2004	David B. Dunger	31611-3A	4111

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,505	DUNGER, DAVID B.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Status of Claims/Amendments:

1. The preliminary amendment filed on 11 January 2004 has been entered. Claims 1-14 have been cancelled and new claims 15-22 have been added. Thus claims 15-22 are pending and are under consideration by the Examiner.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted 11 January 2004 was received and comply with the provisions of 37 CFR §1.97 and § 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

3a. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim rejections- Obviousness-type Double patenting:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4a. Claims 15-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,696,414. Although the conflicting claims are not identical, they are not patentably distinct from each other because: instant claims 15-22 are drawn to a method of increasing insulin sensitivity in a non obese patient or a patient that is not a growth hormone deficient by administering growth hormone or analogue thereof in low doses of 0.008, 0.007, 0.005, 0.003 mg/kg/day, wherein said administration is done in a period of less than one month. Claims 1-5 of U.S. Patent No. 6,696,414 (having the same inventor as the instant application), are drawn to a method of increasing insulin sensitivity in a non-obese, non growth hormone deficient patient by administering growth hormone or an analogue that has an additional methionine residue at the N-terminal end, in low doses of 0.008, 0.007, 0.005, 0.003 mg/kg/day, wherein said administration is done in a period of less than one month. Instant claims 15-22 are identical to claims 1-5, the only difference being that the "growth hormone analogue" recited in claim 1 of U.S. Patent No. 6,696,414, is species to the growth hormone analogue recited in instant claim 15, in that the allowed claim is drawn to an analogue that has an additional methionine residue at the N-terminal end. Thus, since the patented claim 1 recites a species of the analogue recited in instant claim 15, it anticipates claim 15, since species will anticipate a claim to a genus. Allowance of the pending claims, would have the effect of extending the enforceable life of the allowed claims beyond statutory limit.

Claim Rejections Under 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 15-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing insulin sensitivity in a normal subject by administering growth hormone or an analogue of growth hormone, said analogue having an additional methionine reside at the N–terminus in a low dose, does not reasonably provide enablement for a method of increasing insulin sensitivity in a patient by administering growth hormone or an analogue of growth hormone in a low dose.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, practice the invention commensurate in scope with these claims.

Claim 15 is drawn to a method of increasing insulin sensitivity in a patient by administering growth hormone or an analogue of growth hormone in a low dose. Although the instant specification states that "the patient is preferably a normal subject, i.e. not growth hormone deficient patient and/or a non-obese patients". Stedman's Medical Dictionary 27th Edition defines "patient" as "One who is suffering from any disease or behavioral disorder and is under treatment for it". The instant specification states that "Our finding that the effects of low dose GH in normal subjects, (non-obese, non-GH deficient), is of great importance", (page 5, line 26). Thus, the specification

does not disclose the administration of a low dose growth hormone to a patient, neither does it disclose which aliments might said patient suffer from. It only discloses normal subjects that are administered low dose growth hormone to increase insulin sensitivity.

The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, the specification discloses that the administration of growth hormone at low doses in normal subjects, increased insulin sensitivity. However, there is no evidence that administering low dose growth hormone to patients, for example, pre-diabetic patients or obese patients would result in increased insulin sensitivity. There is no guidance as to which population or which medical conditions will respond to low dose growth hormone to increase insulin sensitivity. One skilled in the art would not be able to predict whether the claimed method would be effective on a population that does not consist of normal subjects, and if it does on which population and under what conditions. Furthermore, the instant specification does not disclose a single growth hormone analogue that achieves the same result as growth hormone. There is no disclosure of whether the same dose of "analogue" as growth hormone would be effective. Moreover, growth hormone analogues can be agonists as well antagonists. For example, Rosen et al (U.S. Patent

5,597,709, column 8, lines 29-36, (cited on IDS submitted 11 January 2004).), disclose two human growth hormone splice variants, hGHV-2(88) acts as a growth hormone agonist, while hGHV-3(53) acts as a growth hormone antagonist. Thus undue experimentation would be required of the skilled artisan to test which patient population would benefit from the claimed method and which "analogues" of growth hormone might exhibit the desired activity.

Claim Rejections Under 35 U.S.C. § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

6a. Claims 15, 17-19 are rejected under 35 U.S.C §102(b) as being anticipated by Johannsson, WO 97/38709, (cited on IDS submitted 11 January 2004).

Johannsson discloses a method of administering human growth hormone to male subjects with abdominal/visceral obesity, at 9.5 µg/kg (0.0095 mg/kg) and reduced the dosage in half in the event of side effects (i.e 0.00475 mg/kg). Johannsson showed that these doses of growth hormone increases insulin sensitivity (see page 3, line 100 and also increases IGF-I without substantially increasing the levels of IGFBP-3 (see table 4, after 9 months if administration of GH), these findings are similar to those described in instant example 1. Instant claims 15, 17-19 encompass a method of increasing insulin sensitivity in a patient by administering growth hormone (0.008 mg/kg, 0.005 mg/kg).

Thus, Johannsson reference anticipates these claims in the absence of any evidence to the contrary.

Conclusion:

7. No claims are allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art unit 1647
08 June 2006

Eileen B. O'Hara
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PRIMARY EXAMINER